Using a Social Determinants of Health Framework to Understand Clinical Trial Participation, Long-term Follow-up, and Outcomes Among Women Leaving Jail

By

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Abstract

Background:

Participants from vulnerable populations in most modern clinical trials are underrepresented thereby impacting the generalizability of clinical trial results. This is particularly worrisome – where the intervention is behavioral and the outcome is cancer screening– as both are not well understood but are essential to addressing cancer health disparities and closing gaps in care. We used the World Health Organization's (WHO) social determinants of health to frame results of clinical trial participation, long-term follow-up, and cervical cancer prevention outcomes among vulnerable participants- women leaving incarceration.

Methods:

Three years of follow-up data from a cervical cancer behavioral intervention clinical trial that took place in three county jails between 2014 and 2016 was used to report three outcomes: a) clinical trial completion for women in jails; b) factors associated with best practice community follow-up of women three years after the jail-based intervention; c) cervical cancer health literacy and up-to-date Pap testing at three-year follow-up.

Results:

Of the 261 women who consented to be in the original jail-based clinical trial (about half of the women incarcerated at local jails were recruited on any given day), 114/142 (80.3%) of those assigned to the intervention group completed the intervention. 70/119 (58.8%) of those in the waitlist control group completed the intervention. The primary factor associated with completion of the jail-based intervention was being assigned to the intervention group in Week 1 (by Week 2 when the control group received the intervention, 32 had been discharged from jails

or transferred, 5 were cancelled by the intervention study staff, and 12 for other reasons). One hundred eleven of the 182 (61%) of intervention completers were retained at three years post-intervention and completed all pre, post, and year 3 assessments. Predictors of long-term follow-up included food security and lower utilization of public benefits. Among these participants, with regards to the cervical health literacy, there were statistically significant gains in three of the eight cervical health literacy domains when compared to post-intervention scores and seven of the eight domains when compared to pre-intervention scores ($p < 0.05$). Statistically significant predictors of cervical health literacy scores at year three included age within the confidence domain ($b = 0.03$, $p = 0.030$), education level within the susceptibility domain ($b = – 0.82$, $p = 0.006$), food insecurity within the barrier domain ($b = 0.70$, $p = 0.006$), having a past cervical cancer diagnosis within the severity domain ($b = –1.15$, $p = 0.012$), having received public benefits within the motivation domain ($b = 0.62$, $p = 0.038$) and having experienced racism within the self-efficacy domain ($b = – 0.90$, $p = 0.033$). Despite these improvements to cervical health literacy, up-to-date Pap testing remained steady at 74% compared to 75% at baseline ($p = 0.679$).

Conclusion:

These findings illuminate how WHO social determinants of health predict clinical trial participation, long-term follow-up, and outcomes among vulnerable women. The study offers insights into how clinical trials for behavioral approaches to cancer prevention can be designed, implemented, and evaluated when targeting cancer prevention among vulnerable populations.

Acknowledgements

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Chapter 1: Introduction

Significance

Clinical trials are recognized by the medical community as a gold standard guiding evidence based medical practice and public health policy decisions. Women are one of the fastest growing segments of the incarcerated population, yet incarcerated women are largely underrepresented in modern clinical trials. The consequences of underrepresentation in clinical trials raises concerns over the applicability of results for this vulnerable population and in turn contributes to widening health disparities. The social determinants of health, defined by the World Health Organization (WHO) as "the conditions in which people are born, grow, live, work, and age", are a well-established significant contributor to health inequity. However, the influences exerted by social determinants have not been explored in the context of participation, long-term follow-up, and outcomes in a clinical trial involving incarcerated women. For the benefit of public health, it is imperative to improve access, retention, and outcomes in clinical trials involving incarcerated women. Accomplishing this will require novel approaches that seek to exhaustively understand the contributions of the many complex barriers confronting incarcerated women.

Chapter 2: Literature Review

The Incarcerated Population

Randomized clinical trials serve as a gold standard for determining the efficacy of an intervention, ultimately guiding clinical practice and policy making. It is well established that incarcerated populations are underrepresented in modern clinical trials, raising concerns for the validity of results within these groups (1,2). With more than 9% of the U.S. population having ever been incarcerated and these populations being disproportionately poor and Black or Latinx, this sizable and vulnerable segment of the population confronts poorer health outcomes that clinical trials have largely failed to address (3,4). Incarcerated women, who face additional social stigmatization surrounding gender, represent one of the fastest growing incarcerated demographics having seen a 750% increase in incarceration rates between 1980-2017 (5). The health disparities experienced by incarcerated women are exemplified when considering that a largely preventable condition, cervical cancer, is 4-5 times more prevalent compared to age matched samples of noninstitutionalized women (4). In order to improve health equity, it is critical to examine the forces that limit engagement of this population in clinical trials and how to design those trials to best engage and follow vulnerable women.

Social Determinants of Health Model

In 2010, the World Health Organization's (WHO) Commission on Social Determinants of Health established a theoretical framework to better understand the effects of social determinants on population health. This framework divides social determinants into two broader categories: structural determinants and intermediary determinants. Structural determinants include the social, economic, and political mechanisms that create socioeconomic positions and stratify populations via income, education, occupation, gender, and ethnoracial status.

Consequently, socioeconomic position establishes the intermediary determinants of health which are characterized by differences in exposure and vulnerability specific to that socioeconomic position. Intermediary determinants consist of material circumstances, psychosocial circumstances, behavioral and biological factors, and health system factors. These intermediary determinants then have a direct impact on health status. Importantly, health status can also feedback and influence socioeconomic position by say reducing opportunity for employment due to illness (6). The effects of social determinants on health are observed in United States life expectancy data where higher educational attainment or being White are both associated with longer life expectancy (7). A less abstract example are findings where children who pertained to lower socioeconomic status were found to have less access to recreational facilities and nutritious foods leading to higher rates of being overweight or obese (7). The effects of social determinants have also been applied within the context of a clinical trial. When data from the Antihypertensive and Lipid Lowering Treatment to Prevent Heart Attack Trial (ALLHAT) was stratified into income quintiles, it was found that the lowest income quintile was less likely to achieve blood pressure control and had greater all-cause mortality (8). Having explained the social determinants framework employed in this paper, it is necessary to describe the various levels of barriers that reduce participation in clinical trials for incarcerated women.

Systemic Barriers

There are many barriers limiting participation in clinical trials for incarcerated women. From a systemic standpoint, adoption of subpart C of the protection of human research subjects arose from a need to discontinue unethical research practices that historically exploited prisoners. However, if the proposed research does not fit into one of the four approved categories then 'biomedical or behavioral research shall not involve prisoners as subjects'. Further, there are no

uniform guidelines for inmates' access to clinical research between private, local, state, and federal prisons. Thus, research at a specific facility must comply with administrative policies set forth by the individual site (9). These additional regulations, although they have reversed practices that historically exploitated incarcerated populations, have had the unintended consequence of serving as a justification for funding agencies and biomedical researchers to neglect this population (9). The limited engagement of this population by the research community is made apparent in considering that between 2008 to 2012 only 180 or less than 0.1% of NIH awarded grants were allocated for criminal justice health research (10). Specific to clinical trials, Kouyoumdjian et al. conducted a systematic review of published clinical trials in 14 databases without a time interval applied. Of the 3113 identified clinical trials, 95 involved incarcerated populations and of these only 13 were specific to incarcerated women (11). Aside from these systemic constraints, incarcerated populations also face barriers to enrollment at the level of healthcare providers.

Healthcare Provider Barriers

Clinical trial access hinges largely on healthcare providers offering participation and biases at this level add barriers for incarcerated populations. A study at a large NCI affiliated academic center found that women who were offered participation in breast cancer clinical trials were twice as likely to be White than Black. The primary reason cited for not offering clinical trials to Black women was that they were thought to have "poor performance status and inadequate organ function" and 100% of those who were not offered participation due to "noncompliance" were Black (12). Additionally, a survey of 130 oncologists throughout Pennsylvania found that their perception of patient "mistrust in the medical system" and "a lack of understanding" were the main barriers to enrolling patients in clinical trials (13). In turn,

biases from healthcare providers propagate the lack of representation of incarcerated women in clinical trials. Aside from these more upstream barriers, there are downstream barriers that are also necessary to consider.

Individual Barriers

Finally, at the level of the individual there are many barriers that can preclude participation and retention of incarcerated people in clinical trials. Estimates have found that up to 90% of those released from jails lack health insurance or the ability to pay for medical costs (14,15). Although the affordable care act mandated insurer financial coverage of federally sponsored clinical trials, the mandate did not extend to those insured through Medicaid or the uninsured (16). For these populations, the need to secure alternative funding mechanisms is a deterrent reducing rates of participation (14). However, even if the insurer covers the trial, financial costs associated with participation remain. A report out of Massachusetts General Hospital, found that on average those who participated in clinical trials spent more than $600 per month in additional costs such as travel and lodging (17). This added cost over the long term can be further prohibitive for women with criminal justice histories.

Despite there being a clear need for greater representation of incarcerated women in clinical trials, the literature is sparse on proposed mechanisms that affect this at the level of a single trial. This study seeks explore this topic further by considering the World Health Organization's social determinants of health framework and its influence on participation, retention, and outcomes for women in a jail-based behavioral clinical trial.

Chapter 3: Methods

Study Population

Participants were recruited on a rolling basis from three county jails on both sides of the state border in Kansas City. Convenience sampling was used by posting recruitment flyers in common areas, word-of-mouth by jail staff, and direct conversations between participants and study staff. Inclusion criteria constituted all English-speaking women age 18 years or older in minimum or medium security housing. As a low risk behavioral intervention, exclusion criteria were limited, with only one interested person being excluded on the grounds that their psychological distress impeded their ability to provide informed consent. Ultimately, 182 women completed the intervention and 78 women did not. Of the 182 women who completed the intervention, 111 women completed all pre-intervention, post-intervention, and yearly follow-up surveys (18).

Study Design

This prospective behavioral clinical trial was conducted as a waitlist control design to mitigate ethical concerns of having an untreated control group in this vulnerable population with a low-risk behavioral cancer prevention intervention. Once consented, participants completed our 158-item baseline survey consisting of sociodemographic information, health system navigation, and histories of mental health, criminal justice involvement, and sexual and reproductive health. Additionally, baseline and all subsequent surveys incorporated questions derived from the Pap Knowledge Scale (19), the Health Belief Model Scale for Cervical Cancer and Pap Smear Test (20), the Self-Efficacy Scale for Pap Smear Screening Participation Randomization (21), and three questions the team developed based on previous work (22). These questions allowed us to operationalize cervical health literacy into the following domains: knowledge, self-efficacy,

confidence, and beliefs. Beliefs were then further categorized into benefits, barriers, severity, susceptibility, and motivation (20). Trial randomization was achieved based on seating during consent, with every other person being assigned to the intervention arm or the waitlist control arm. Those assigned to the intervention arm began the intervention program the same day (day 1) and following the last session on day 5, completed an 82-item post-intervention survey. The waitlist control group began their intervention the following week but, prior to commencing the program on day 1, were asked to complete a 73-item pre-intervention survey. The intervention was initially evaluated by observing changes in cervical health literacy between the intervention arm's baseline and post-intervention surveys compared with the control arm's baseline and pre-intervention surveys. Since all participants had received the intervention by yearly follow-up, a pre-post design was used to evaluate cervical health literacy outcomes as well as changes in up-to-date Pap testing. A 146-item yearly follow-up survey was administered at years 1, 2, and 3 to evaluate cervical health literacy using the aforementioned tools. Additional questions on up-to-date Pap screening along with relevant changes to sociodemographic information, health system navigation, criminal justice involvement, and mental, reproductive, and sexual health histories were also included in the follow-up survey (18).

Intervention

The Sexual Health Empowerment (SHE) intervention was designed to increase cervical health literacy and utilization of cervical cancer screening for incarcerated women. In a small group setting of 2 to 10 participants, the intervention was organized into 2-hour daily sessions over the course of 5 days. Sessions were facilitated by a sexual health educator and assistant but emphasized participants' collective knowledge and experiences as a means of group empowerment (18).

Measures

Survey data collected at baseline and through 3 years of follow-up was used to report on the three dependent variables for this study. These included clinical trial completion, retention at year three, and cervical cancer prevention outcomes including both sustained cervical health literacy and up-to-date Pap screening. We used the World Health Organization's social determinants of health framework to establish independent variables and quantify their effects on our dependent variables. Under this framework we were able to examine both structural determinants and intermediary determinants. Structural determinants constituted age, ethnoracial status, education, and occupation. Intermediary determinants are further subcategorized into material circumstances, behavioral and biological factors, psychosocial factors, and health system factors. Material circumstances comprised of housing, consumption potential, food security, history of exchanging sex, and transportation. Behavioral and biological factors were alcohol and substance use, history of mental illness, history of sexually transmitted infection, history of abnormal pap test, and history of cervical cancer. Psychosocial factors included lifetime months incarcerated, recipient of public benefits, experiences of discrimination, and history of child physical and sexual abuse. Finally, health system factors were insurance status, access to a primary care doctor, and having a medical home.

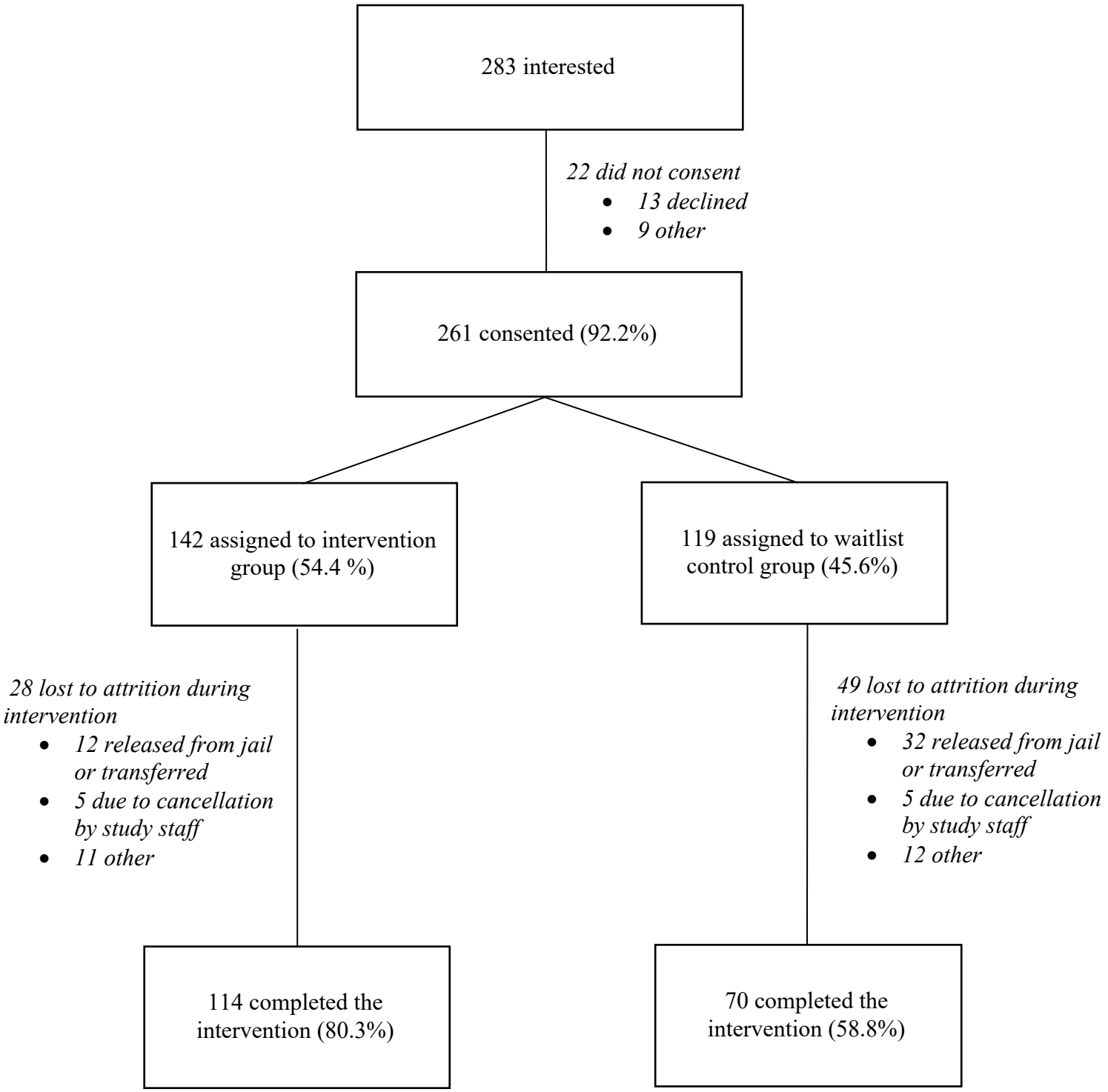
Statistical Analysis

Descriptive statistics were utilized to summarize the structural and intermediary determinants of health, separately for participants who completed the intervention (n = 182) and who did not (n = 79); for participants who completed the intervention and were retained at year 3 (n = 111) and who completed the intervention but were lost to follow-up (n = 71). Bivariate tests

(independent-samples *t*-test, chi-square or Fisher's exact test as appropriate) were conducted to compare each variable between these participant subgroups. The participants' health literacy (knowledge, benefits, barriers, severity, susceptibility, motivation, self-efficacy, confidence) and Pap screening were summarized at three time points—pre-intervention, post-intervention, and 36 months after release from jail. Paired-samples *t*-test was performed to examine the change in each variable over the 3-year period Further, general linear modeling was used to examine the effects of the structural and intermediary determinants (predictors) on health literacy (outcome) after release from jail. Specifically, an ordinary least squares regression model was fitted for each of the eight health literacy scores. In line with an intent-to-treat approach, when there were missing observations due to either attrition or non-response, all available data from partial measurements were included in the analysis. All analyses were conducted using SAS 9.4 (SAS Institute, 2002–2012).

Chapter 4: Results

Figure 1. Intervention participation flowchart.



Baseline

Of the 261 women consented for the study, 182 completed the intervention and 79 did not. The participant flow chart above does not fully reflect these values as errors were identified following publication. These included four duplicate participants, one woman who completed the intervention under the wrong group assignment, and one woman who completed the posttest at four weeks as opposed to one week later (23). Strikingly, 44 participants (16.8%) did not complete the intervention as a result of being released from jail or transferred to another facility. This is especially apparent in the wait-list control group where 32 participants or nearly 27% did not complete the intervention for this reason. These findings reflect the principle explanation behind those who completed the intervention and those that did not. It is also worth noting the relatively high percentage of completion (80.3%) observed in the immediate intervention group. Such findings allude to a strong interest in completing the behavioral clinical trial intervention by our sample.

In considering the structural determinants of health, there were no statistically significant differences observed between the intervention completion and intervention non-completion groups. The mean age for both groups was around 33 years and both groups had similar ethnoracial compositions with around half identifying as an ethnoracial minority and the other half identifying as white.

Similarly, the intermediary determinants within the domains of behavioral and biological factors, psychosocial factors, and health system factors yielded no statistically significant differences between the intervention completion and intervention non-completion groups. Within behavioral and biological factors, both groups had means exceeding 60% for history of substance dependence and history of sexually transmitted infection (STI) and greater than 70% for history

of mental illness. Considering psychosocial factors, while mean lifetime months incarcerated appear different between the groups (25.55 months for the intervention completers and 21.13 months for non-completers), there is a tremendous amount of variance with standard of deviation nearly doubling the means (± 47.77 for intervention completers and ± 39.45 for non-completers). Under health system factors, more than half of the women in both groups reported having no health insurance and less than half of the women in both groups reported having a primary care doctor.

While no statistically significant differences were observed between the two groups in the aforementioned domains, there were differences within the domain of material circumstances. Of women who completed the intervention, 52.6% reported not having enough money to take care of basic monthly needs. In comparison, 67.5% of women who did not complete the intervention reported not having enough money to take care of basic monthly needs. This constituted a statistically significant difference at a threshold of 0.05 with a calculated p-value of 0.028. Other interesting trends within this domain was greater reporting of food insecurity, history of exchanging sex, and not having a reliable source of transportation among the intervention non completion group.

Table 1. WHO based determinants of health for those who completed the clinical trial intervention versus those who did not

	Total (*N*=261)	**Intervention completed (*n*=182)**	**Intervention not completed (*n*=79)**	***p*[a]**
Structural Determinants				
Age	33.70 ± 9.95	33.83 ± 9.50	33.39 ± 10.97	0.756
Ethnoracial status				0.733
White	128 (51.0 %)	92 (51.7 %)	36 (49.3 %)	
Ethnoracial minority	123 (49.0 %)	86 (48.3 %)	37 (50.7 %)	
Education				0.987
Less than high school	88 (35.1 %)	62 (35.0 %)	26 (35.1 %)	
High school or beyond	163 (64.9 %)	115 (65.0 %)	48 (64.9 %)	
Employment status				0.681

Employed	85 (35.3 %)	61 (36.1 %)	24 (33.3 %)	
Unemployed	156 (64.7 %)	108 (63.9 %)	48 (66.7 %)	

Intermediary Determinants

	Total (*N*=261)	**Intervention completed (*n*=182)**	**Intervention not completed (*n*=79)**	***p*[a]**
Material Circumstances				
Housing stability	179 (73.1 %)	126 (73.7 %)	53 (71.6 %)	
Housing instability	66 (26.9 %)	45 (26.3 %)	21 (28.4 %)	
Neighborhood				0.477
Fear of violence	101 (40.1 %)	68 (38.6 %)	33 (43.4 %)	
No fear of violence	151 (59.9 %)	108 (61.4 %)	43 (56.6 %)	
Consumption potential				**0.028**
Basic needs financial stability	107 (42.8 %)	82 (47.4 %)	25 (32.5 %)	
Basic needs financial instability	143 (57.2 %)	91 (52.6 %)	52 (67.5 %)	
Food insecurity	70 (27.8 %)	46 (26.3 %)	24 (31.2 %)	0.425
No reliable source of transportation	82 (32.2 %)	52 (29.2 %)	30 (39.0 %)	0.126
History of exchanging sex	91 (36.8 %)	60 (34.7 %)	31 (41.9 %)	0.282
Behavioral and Biological Factors				
History of harmful alcohol use	132 (50.6 %)	94 (51.7 %)	38 (48.1 %)	0.599
History of substance dependence	163 (62.5 %)	112 (61.5 %)	51 (64.6 %)	0.644
History of mental illness[b]	191 (73.2 %)	133 (73.1 %)	58 (73.4 %)	0.955
History of STIs[c]	163 (62.5 %)	115 (63.2 %)	48 (60.8 %)	0.710
History of abnormal Pap test	126 (51.4 %)	95 (54.9 %)	31 (43.1 %)	0.091
Cervical cancer diagnosis	30 (12.0 %)	24 (13.9 %)	6 (7.8 %)	0.172
Psychosocial Factors				
Lifetime months incarcerated	24.20 ± 45.36	25.55 ± 47.77	21.13 ± 39.45	0.441
Received public benefits	133 (63.3 %)	87 (62.6 %)	46 (64.8 %)	0.754
Experienced racism	101 (42.3 %)	70 (41.9 %)	31 (43.1 %)	0.870
Child physical or sexual abuse	74 (56.5 %)	50 (57.5 %)	24 (54.6 %)	0.750
Health System factors				
Pap screening in past three years	174 (74.7 %)	124 (74.7 %)	50 (74.6 %)	0.991
Has primary care doctor	103 (40.7 %)	69 (39.0 %)	34 (44.7 %)	0.393
Has medical home	183 (72.3 %)	125 (71.0 %)	58 (75.3 %)	0.482
No insurance coverage	133 (55.7 %)	96 (57.5 %)	37 (51.4 %)	0.384

Notes.
M ± *SD*; *n* (%)
[a] *p* values less than 0.05 are in boldface.
[b] Lifetime diagnosis of depression, anxiety, bipolar disorder, or post-traumatic stress disorder by a clinician.
[c] Lifetime diagnosis of hepatitis B or C, human immunodeficiency virus, syphilis, gonorrhea, chlamydia, trichomoniasis, herpes, or HPV by a clinician.

Three-year follow-up

Out of the 182 women who completed the intervention, 111 completed every survey through follow-up at year three. Structural determinants including age, education, and employment status were fairly similar to the baseline characteristics reported above and there were no statistically significant differences in these between the retained group and the group lost to follow-up. Surprisingly, an observable trend is the greater proportion of White participants (59.7%) being in the lost to follow-up group coupled with a lower proportion of Ethnoracial minorities (40.3%) being lost to follow-up. Although this did not constitute a statistically significant difference with a p-value of 0.096, this finding was unexpected for this study.

Within the intermediary determinants, the domains of behavioral and biological factors and health system factors yielded no statistically significant differences between the retention and loss to follow-up groups. Group averages for history of substance abuse, history of STI, and history of mental illness remained stable as did reporting having a primary care doctor and not having insurance. However, in analyzing the domains of psychosocial factors and material circumstances, there were some statistically significant differences between the retention and loss to follow-up groups. Of the psychosocial factors, it was striking to find that 100% of available data reported in the loss to follow-up group received public benefits compared to the 51.4% reported in the retention group (p-value < 0.001). Interestingly, there was also a statistically significant difference in the reported rates of child physical or sexually abuse with 66.7% in the retained group and 44.4% in the loss to follow-up group reporting such a history ($p = 0.039$). In considering material circumstances, food insecurity was a statistically significant difference with 19.6% reporting food insecurity in the retention group compared to 36.8%

reporting in the loss to follow-up group (p = 0.012). Although basic monthly need financial instability was a statistically significant difference in the baseline analysis, such a difference did not carryover between the retention and loss to follow-up groups.

Table 2. WHO based determinants of health for those who were retained at year 3 versus those who were lost to follow-up

	Total (*n*=182)	**Retained at year 3 (*n*=111)**	**Lost to follow-up (*n*=71)**	***p*[a]**
Structural Determinants				
Age	33.84 ± 9.48	34.07 ± 10.04	33.47 ± 8.57	0.673
Ethnoracial status				0.096
White	92 (51.7 %)	52 (46.9 %)	40 (59.7 %)	
Ethnoracial minority	86 (48.3 %)	59 (53.2 %)	27 (40.3 %)	
Education				0.953
Less than high school	62 (35.0 %)	38 (34.9 %)	24 (35.3 %)	
High school or beyond	115 (65.0 %)	71 (65.1 %)	44 (64.7 %)	
Employment status				0.767
Employed	61 (36.1 %)	37 (35.2 %)	24 (37.5 %)	
Unemployed	108 (63.9 %)	68 (64.8 %)	40 (62.5 %)	
Intermediary Determinants				
Material Circumstances				
Housing				0.561
Housing stability	126 (73.7 %)	79 (75.2 %)	47 (71.2 %)	
Housing instability	45 (26.3 %)	26 (24.8 %)	19 (28.8 %)	
Neighborhood				0.150
Fear of violence	68 (38.6 %)	38 (34.6 %)	30 (45.5 %)	
No fear of violence	108 (61.4 %)	72 (65.5 %)	36 (54.6 %)	
Consumption potential				0.708
Basic needs financial stability	82 (47.4 %)	50 (46.3 %)	32 (49.2 %)	
Basic needs financial instability	91 (52.6 %)	58 (53.7 %)	33 (50.8 %)	
Food insecurity	46 (26.3 %)	21 (19.6 %)	25 (36.8 %)	**0.012**
No reliable source of transportation	52 (29.2 %)	29 (26.4 %)	23 (33.8 %)	0.288
History of exchanging sex	60 (34.7 %)	39 (36.5 %)	21 (31.8 %)	0.534
Behavioral and Biological Factors				
History of harmful alcohol use	94 (51.7 %)	56 (50.5 %)	38 (53.5 %)	0.686
History of substance dependence	112 (61.5 %)	72 (64.9 %)	40 (56.3 %)	0.249
History of mental illness[a]	133 (73.1 %)	82 (73.9 %)	51 (71.8 %)	0.762
History of STIs[b]	115 (63.2 %)	72 (64.9 %)	43 (60.6 %)	0.557
History of abnormal Pap test	95 (54.9 %)	57 (55.9 %)	38 (53.5 %)	0.759
Cervical cancer diagnosis	24 (13.9 %)	14 (13.2 %)	10 (14.9 %)	0.750

	Total (*n*=182)	Retained at year 3 (*n*=111)	Lost to follow-up (*n*=71)	*p*[a]
Psychosocial Factors				
Lifetime months incarcerated	25.55 ± 47.77	23.51 ± 39.02	28.75 ± 59.12	0.517
Received public benefits	87 (62.6 %)	55 (51.4 %)	32 (100.0 %)	<**0.001**
Experienced racism	70 (41.9 %)	45 (43.7 %)	25 (39.1 %)	0.556
Child physical or sexual abuse	50 (57.5 %)	34 (66.7 %)	16 (44.4 %)	**0.039**
Health System factors				
Pap screening in past three years	124 (74.7 %)	78 (74.3 %)	46 (75.4 %)	0.872
Has primary care doctor	69 (39.0 %)	44 (41.1 %)	25 (35.7 %)	0.471
Has medical home	125 (71.0 %)	80 (73.4 %)	45 (67.2 %)	0.376
No insurance coverage	96 (57.5 %)	55 (53.9 %)	41 (63.1 %)	0.243

Notes.
M ± *SD*; *n* (%)
[a] *p* values less than 0.05 are in boldface.
[b] Lifetime diagnosis of depression, anxiety, bipolar disorder, or post-traumatic stress disorder by a clinician.
[c] Lifetime diagnosis of hepatitis B or C, human immunodeficiency virus, syphilis, gonorrhea, chlamydia, trichomoniasis, herpes, or HPV by a clinician

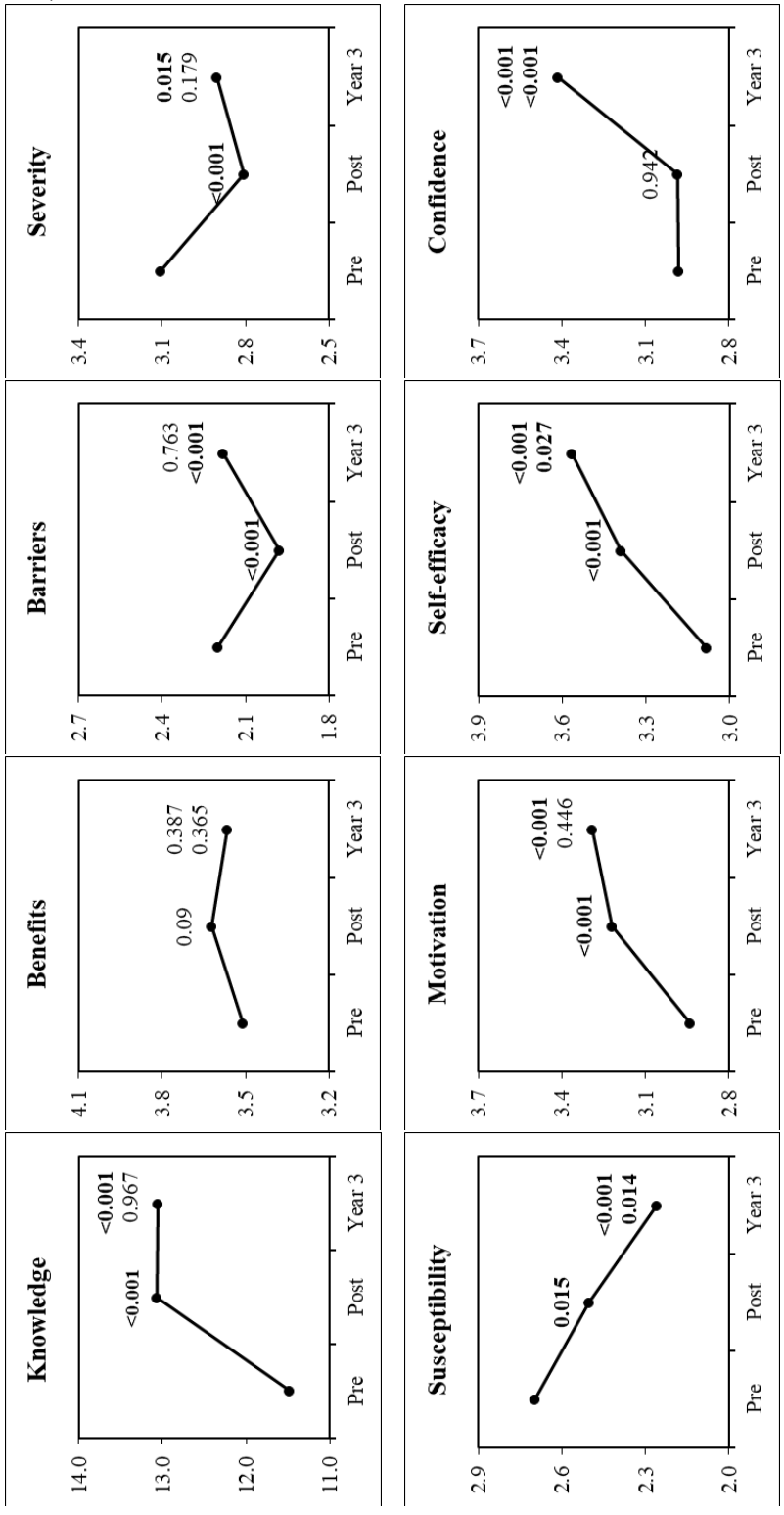
Outcomes

When examining the primary intent of the intervention, increasing cervical health knowledge and up-to-date Pap testing, there were some paradoxical and unforeseen findings. As depicted in figure 2, one of the key findings is the long-term sustained cervical health knowledge following the brief intervention. At year three, every domain with the exception of benefit demonstrated statistically significant improvement from pre-intervention scores ($p < 0.05$). Such findings are consistent with the original study, where again benefit was one of two domains to not show a statistically significant improvement, demonstrating the prolonged impact of the intervention. When comparing post-intervention scores with year three scores, there were statistically significant improvements in the domains of susceptibility ($p = 0.014$), self-efficacy ($p = 0.027$), and perhaps most impressive were the dramatic gains in confidence ($p < 0.001$), a

domain that was essentially equivalent between pre and post intervention scores. In spite of the improvements to cervical health literacy, up-to-date Pap testing was not significantly different (see figure 3) with 74% of participants reporting up-to-date Pap testing at year three compared to 75% at the pre-intervention phase. Such a finding is curious and warrants further exploration to determine the cause.

Results from the linear model (table 3) brought to light the predictive value of WHO based social determinants when applied to the dependent variable of cervical health literacy. Although there were no statistically significant predictors for the domains of knowledge and benefits, the other domains all had an independent variable of predictive value. Independent variables with a positive linear relationship included food insecurity with the barriers domain ($b = 0.70$, $p = 0.006$), receiving public benefits with the motivation domain ($b = 0.62$, $p = 0.038$), and age with the confidence domain ($b = 0.03$, $p = 0.03$). However, it is important to note that a 0.03 gain in confidence score for each year increase is minimal and the standard error of 0.01 emphasizes the precision of the model for generating a statistically significant result. Independent variables that had a negative linear relationship included a past cervical cancer diagnosis in the severity domain ($b = -1.15$, $p = 0.012$), having attained a high school education or beyond in the susceptibility domain ($b = -0.82$, $p = 0.006$), and having experienced racism in the self-efficacy domain ($b = -0.90$, $p = 0.033$)

Figure 2. Women's health literacy scores pre-intervention, post-intervention, and at year 3 (n = 111).



Note.
The value at the "Post" point is the p-value of test for comparing pre-intervention vs. post-intervention; the upper and lower values at the "Year 3" point are the p-values of test for comparing pre-intervention vs. year 3 and comparing post-intervention vs. year 3, respectively.
p values less than 0.05 are in boldface.

Table 3. Prediction for women's health literacy scores

	DV = knowledge			DV = Benefits			DV = Barriers			DV = Severity		
Parameter	*b*	*SE*	*p*	*b*	*SE*	*p*	*b*	*SE*	*p*	*b*	*SE*	*p*
Intercept	12.94	1.77	**<0.001**	3.81	0.38	**<0.001**	2.47	0.59	0.000	3.35	0.67	**<0.001**
Structural Determinants												
Age	−0.02	0.03	0.573	0.00	0.01	0.853	0.00	0.01	0.921	0.00	0.01	0.868
White	0.36	0.70	0.611	−0.10	0.15	0.524	0.25	0.23	0.281	0.06	0.27	0.825
High school or beyond	0.61	0.65	0.358	−0.03	0.14	0.812	−0.36	0.22	0.102	−0.14	0.25	0.579
Employed	0.41	0.67	0.545	−0.20	0.15	0.185	0.12	0.22	0.589	−0.15	0.26	0.566
Intermediary Determinants												
Material Circumstances												
Housing stability	0.56	0.88	0.527	0.01	0.19	0.974	−0.31	0.29	0.289	−0.67	0.33	0.052
Neighborhood violence	0.44	0.70	0.531	0.01	0.15	0.955	−0.11	0.23	0.622	0.22	0.27	0.402
Basic financial stability	−0.11	0.66	0.869	0.07	0.14	0.613	−0.09	0.22	0.688	0.00	0.25	0.998
Food insecurity	−1.23	0.73	0.101	−0.27	0.16	0.092	0.70	0.24	**0.006**	0.35	0.28	0.216
No transportation	0.73	0.92	0.436	0.15	0.20	0.452	−0.08	0.31	0.796	0.19	0.35	0.595
Exchanging sex	0.41	0.76	0.593	0.04	0.16	0.803	−0.01	0.25	0.984	0.02	0.29	0.941
Behavioral and Biological Factors												
Harmful alcohol use	0.46	0.67	0.498	−0.08	0.14	0.595	0.05	0.22	0.830	−0.13	0.25	0.625
Substance dependence	0.22	0.64	0.730	−0.18	0.14	0.197	−0.05	0.21	0.832	0.23	0.24	0.358
Mental illness	0.70	0.72	0.335	0.18	0.15	0.250	−0.22	0.24	0.353	−0.25	0.27	0.369
Abnormal Pap test	−1.03	1.96	0.604	−0.67	0.42	0.124	1.12	0.65	0.095	1.32	0.75	0.086
Cervical cancer diagnosis	−0.10	1.14	0.930	−0.15	0.25	0.548	−0.50	0.38	0.196	−1.15	0.43	**0.012**
Psychosocial Factors												
Past year reincarcerated	0.62	0.84	0.467	0.09	0.18	0.628	0.01	0.28	0.972	−0.35	0.32	0.281
Public benefits	0.01	0.68	0.991	0.17	0.15	0.252	0.00	0.23	0.998	0.20	0.26	0.453
Experienced racism	0.13	0.73	0.861	−0.07	0.16	0.669	0.36	0.24	0.141	0.24	0.28	0.397
Health System factors												
Pap screening in past three years	−0.92	0.83	0.275	−0.17	0.18	0.339	0.07	0.27	0.813	0.14	0.32	0.657
No insurance coverage	−0.44	0.73	0.551	0.11	0.16	0.505	−0.32	0.24	0.188	−0.46	0.28	0.108

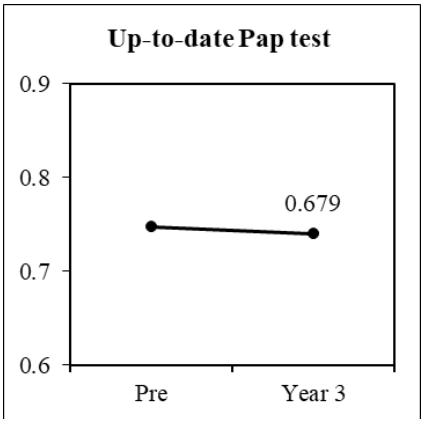
Note.
p values less than 0.05 are in boldface.

Table 3. Prediction for women's health literacy scores (continue)

	DV = Susceptibility			DV = Motivation			DV = Self-efficacy			DV = Confidence		
Parameter	*b*	*SE*	*p*	*b*	*SE*	*p*	*b*	*SE*	*p*	*b*	*SE*	*p*
Intercept	4.17	0.76	**<0.001**	2.42	0.74	**0.003**	2.41	0.98	**0.019**	2.54	0.68	**0.001**
Structural Determinants												
Age	−0.02	0.01	0.108	0.02	0.01	0.194	0.03	0.02	0.095	0.03	0.01	**0.030**
White	0.56	0.30	0.072	−0.26	0.29	0.391	−0.67	0.39	0.093	−0.47	0.27	0.088
High school or beyond	−0.82	0.28	**0.006**	−0.31	0.27	0.268	0.08	0.36	0.819	0.19	0.25	0.462
Employed	−0.17	0.29	0.568	0.00	0.28	0.995	−0.03	0.37	0.933	0.41	0.26	0.125
Intermediary Determinants												
Material Circumstances												
Housing stability	−0.77	0.38	0.050	0.20	0.37	0.591	−0.16	0.49	0.750	−0.31	0.34	0.362
Neighborhood violence	−0.12	0.30	0.686	−0.17	0.29	0.569	−0.43	0.39	0.276	−0.40	0.27	0.148
Basic financial stability	−0.32	0.28	0.269	0.47	0.28	0.096	0.74	0.37	0.050	0.15	0.25	0.557
Food insecurity	0.38	0.31	0.235	−0.32	0.30	0.295	−0.28	0.40	0.496	−0.38	0.28	0.185
No transportation	−0.31	0.40	0.447	0.05	0.39	0.902	0.14	0.51	0.783	0.47	0.36	0.191
Exchanging sex	−0.11	0.32	0.743	−0.37	0.32	0.247	−0.26	0.42	0.539	0.08	0.29	0.794
Behavioral and Biological Factors												
Harmful alcohol use	0.38	0.29	0.191	0.00	0.28	0.989	0.08	0.37	0.830	−0.22	0.26	0.395
Substance dependence	−0.08	0.28	0.783	−0.31	0.27	0.253	−0.14	0.36	0.706	0.24	0.25	0.348
Mental illness	−0.55	0.31	0.084	0.42	0.30	0.169	0.38	0.40	0.346	0.00	0.28	0.992
Abnormal Pap test	1.40	0.84	0.106	−0.45	0.82	0.591	−1.47	1.09	0.186	−0.33	0.75	0.664
Cervical cancer diagnosis	−0.21	0.49	0.665	−0.20	0.48	0.673	0.79	0.63	0.222	0.29	0.44	0.509
Psychosocial Factors												
Past year reincarcerated	−0.01	0.36	0.982	0.40	0.35	0.265	0.03	0.47	0.941	0.29	0.32	0.376
Public benefits	0.15	0.29	0.624	0.62	0.29	**0.038**	0.08	0.38	0.826	−0.16	0.26	0.545
Experienced racism	0.51	0.31	0.114	−0.01	0.31	0.974	−0.90	0.40	**0.033**	−0.26	0.28	0.353
Health System factors												
Pap screening in past three years	0.17	0.36	0.646	−0.37	0.35	0.293	0.28	0.46	0.552	0.39	0.32	0.226
No insurance coverage	−0.40	0.31	0.207	0.56	0.31	0.077	0.19	0.40	0.632	−0.53	0.28	0.065

Note.
p values less than 0.05 are in boldface.

Figure 3. Proportion of up-to-date Pap screening pre-intervention (n = 261) and at year 3 (n = 111)



Note.
The value at the "Year 3" point is the *p*-value of test for comparing pre-intervention vs. year 3. *p* values less than 0.05 are in boldface.

Chapter 5: Discussion

In revisiting data from a clinical trial centered on incarcerated women, there were WHO defined social determinants of health, specifically related to lower socioeconomic standing, that differed between the comparison groups over the long-term. Further, social determinants of health had predictive value for one of the primary outcomes of the original study, cervical health literacy. These findings indicate that even among one of the most vulnerable populations, women with criminal justice histories, social determinants are still associated with stratification and lead to differential outcomes. This is in line with previous works where social determinants stratified and affected health outcomes of another vulnerable population, immigrants (24). In the context of clinical trials, the ALLHAT social determinant analysis also had similar findings where those pertaining to the lowest income quintile were less likely to adhere to scheduled long-term follow-up visits (8). Such findings signify critical considerations for retention strategies in future clinical trials involving incarcerated women. If identified at baseline, allocating more resources to participants with the poorest socioeconomic standing may translate to greater retention and in turn yield more valid generalizable results. The ALLHAT trial highlights the consequences of failing to account for these factors with a 1:5 participant ratio of the lowest to highest income quintiles respectively (8). Thus, if our society prioritizes equitable and evidence-based healthcare, it is imperative to address the social determinants of health when designing and implementing clinical trials, especially when the trial involves a vulnerable underrepresented population.

The present study also generated other notable results that merit further discussion. One variable that was statistically significant and contrary to expectations was a history of child physical or sexual abuse associated with the long-term follow-up group. The literature is extensive on how a history of child abuse translates to worse health outcomes especially in

mental health (25). Nonetheless, there was not a significant difference between the groups in terms of a history of mental illness. Taking into account the high prevalence of histories of child physical or sexual abuse coupled with a relatively small sample size, this finding may represent a sampling error. Another possible explanation for these findings is that women with histories of sexual abuse might perceive a greater need for their own sexual empowerment, endearing them to an intervention like SHE more so than women who did not experience such abuse. The literature supports this notion with findings that incarcerated women's support from other prisoners was integral to their wellbeing (26). For participants retained over the course of the three years, the sustained and in some cases improved cervical health literacy domain scores were impressive. This points to the profound long-term impact that the 10 hour SHE intervention had on our participants. Additionally, the trend that ethnoracial minorities had greater long-term retention than white participants may reflect an approach used in the SHE intervention, as both the principle investigator and project manager are women of color. Future clinical trials with incarcerated women could evaluate how ethnoracial congruency between participants and study coordinators influences long-term retention. All in all, these findings allude to the potential for replicating this approach in successfully designing behavioral clinical trials with incarcerated women.

Surprisingly, sustained cervical health literacy scores did not correspond to a higher percentage of up-to-date Pap testing in our sample. However, prior to considering potential explanations for this finding, it is worth mentioning that the percentage did not appreciably decline and was just below the 76.1% national average of up-to-date Pap testing in women aged 18-44 (27). Although this study applied WHO social determinants to the context of a clinical trial, the social determinants of health arose from repeated observations that social positionality,

when controlling for other factors, confers differential health outcomes. Women with criminal justice histories generally experience a greater proportion of the social determinants of health risk factors and this could account for the discrepancy. Since Pap testing rates are similar to national averages but cervical cancer prevalence is drastically higher among incarcerated women, future studies should be conducted to identify the mechanisms accounting for such differential outcomes. It is possible that empowering participants with cervical health literacy may in and of itself be insufficient to overcome the structural forces that propel worse outcomes for incarcerated women

There are limitations in this study to acknowledge. Overall, the comparative analysis in this study identified lower than expected statistically significant differences between groups. One reason for this was the limitation in taking a retrospective analytical approach. Such an approach was constraining because it did not allow alterations to the design to account for rapid jail turnover, a confounding variable that greatly affected the baseline comparison. Moreover, the sample size was fairly small particularly at the stage of the long-term follow-up analysis. A larger sample size would reduce the type II error rate and hence, a larger study may detect a greater number of differences using the same approach. A final limitation is that incomplete data was used for analysis due to missing observations (i.e., nonresponses on survey items). This likely reduced the statistical power of conclusions made in this paper and reduced the true representativeness of the sample. However, the data appears to be, at least, missing at random and thus minimal bias was introduced to the analysis.

Ultimately, there is a crucial need to expand clinical trials involving incarcerated women to realize equitable healthcare. Understanding factors influencing participation, retention, and outcomes in clinical trials is a requisite step for greater engagement of this population by the

research community. This study was the first to provide insight on these factors at the level of a single clinical trial comprised of incarcerated women. Future investigations can build off of this work by accounting for factors identified in this study to further characterize the barriers incarcerated women face.

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